

**REMARKS****STATUS OF THE CLAIMS**

Claims 1-38 were pending. Following entry of this Amendment, claims 5, 10-13, 17, 20, 24, and 25-28 will be pending. Claims 1 and 3, 14, 16, and 18 have been canceled in this amendment. Claims 2, 4, 6-9, 15, 19, 21-23, and 29-38 have been canceled in this amendment as they were withdrawn from consideration as being drawn to a non-elected invention by the Examiner. New claim 39 has been added. Claims 5, 10-13, 17, 20, 24, and 27-28 have been amended. .

**I. ABSTRACT**

The Examiner objected to the specification as lacking an abstract.

Applicants have enclosed a new abstract as a separate sheet. Applicants request that this objection be withdrawn.

**II. OBJECTION TO THE BRIEF DESCRIPTION OF DRAWINGS**

The Examiner has objected to the lack of the heading "Brief Description of the Drawings" and that has alleged that Figures 3, 6, and 7 must also be described in the Brief Description of the Drawings as Figure 3A-I, Figure 6A-C, and Figure 7A-B.

Applicants have amended the specification to insert the heading "Brief Description of the Drawings." Applicants contend that Figures 3, 6, and 7 are sufficiently described under the "Brief Description of the Drawings" as sufficient detail is provided with regard to the figures and the figures are adequately annotated. Applicants request that this objection be withdrawn.

**III. OBJECTION UNDER 37 C.F.R. §§ 1.821-1.825**

The Examiner has objected to Figures 1 and 4, and claim 14 as not complying with 37 CFR § 1.821(d) for the not containing a recitation of a SEQ ID NO:.

Applicants have canceled claim 14. Figure 1 has been amended to delete "human beta 3 ORF" and insert therefore "SEQ ID NO:4 (376-1023)", and to delete "Rat Beta 3 ORF" and insert therefore "SEQ ID NO:3 (363-1010)." Replacement sheets for Figure 1

and Figure 4 are enclosed herewith. Figure 4 has been amended to delete “rat  $\beta 3$ ” and “human  $\beta 3$ ”, and insert therefor “SEQ ID NO: 1”, and “SEQ ID NO: 2,” respectively. Applicants request that this objection be withdrawn.

#### **IV. REJECTION UNDER 2nd PARAGRAPH OF 35 U.S.C. § 112 - DEFINITENESS**

The Examiner has rejected claims 1, 3, 5, 10-14, 16-18, 20, and 24-28 under 35 U.S.C. § 112, second paragraph, for various different bases. Each rejection will be addressed below.

A. The Examiner has rejected claims 1, 3, 14, 18 and 20, under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the recitation of  $\beta$ -3 subunit as not providing sufficient structural limitations on the claims.

Applicants have canceled claims 1, 3, 14 and 18. Claim 20 has been amended to clarify that the amplification primers consist of “of at least 10 consecutive nucleotides of a nucleic acid selected from the group consisting of a polynucleotide encoding a peptide of SEQ ID NO: 5, 7, 9, 11, 13, 15, 17, 19, 20, 22, 24, 25-32, or 46, or a sequence complementary thereto.” Applicants therefore respectfully submit that claim 20, as amended, provides sufficient structural limitations to be definite under 35 U.S.C. § 112, 2nd paragraph. Accordingly Applicants respectfully request that this rejection under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

B. The Examiner has rejected claim 14 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because “SEQ ID NO:876 in WO9845435” and “NOAA685538” must be identified by SEQ ID NOS under 37 CFR § 1.821-1.825.

Claim 14 has been canceled. Accordingly Applicants respectfully request that this rejection under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

C. The Examiner has rejected claim 18 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because the method steps allegedly do not achieve the goal of the preamble. The Examiner has also mentioned that the primer and

the hybridization conditions are not disclosed. Claim 20 is also rejected for failing to disclose the primers.

Applicants have amended claim 20 to clarify that the amplification primers consist of “of at least 10 consecutive nucleotides of a nucleic acid selected from the group consisting of a polynucleotide encoding a peptide of SEQ ID NO: 5, 7, 9, 11, 13, 15, 17, 19, 20, 22, 24, 25-32, or 46, or a sequence complementary thereto.” Applicants therefore respectfully submit that claim 20, as amended, provide sufficient structural limitations to be definite under 35 U.S.C. § 112, 2nd paragraph. Claim 18 has been canceled. Accordingly Applicants respectfully request that this rejection under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

D. The Examiner has rejected claim 24 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because the “stringent hybridization” conditions were not specified.

Applicants have amended claim 24 to recite that the “hybridization reaction is conducted at 65°C in the presence of 6 x SSC buffer, 5 x Denhardt’s solution, 0.5 % SDS and 100 µg/ml of salmon sperm DNA.” This amendment finds support in the specification on page 10, lines 18-21. Applicants therefore respectfully submit that claim 24, as amended, is definite under 35 U.S.C. § 112, 2nd paragraph. Accordingly Applicants respectfully request that this rejection under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

E. The Examiner has rejected claims 18, 20, 24, 27, and 28 under 35 U.S.C. § 112, second paragraph, for depending on a non-elected claim.

Applicants have amended claims 20, 24, 27, and 28, so that they do not depend on a non-elected claim. Claim 18 has been canceled. Accordingly Applicants respectfully request that this rejection under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

F. The Examiner has rejected claims 5, 10-13, 16-17, and 25-26 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for depending on an indefinite base (or intermediate) claim.

Claims 5, 10-13 originally depended on claim 1. Claim 1 has been canceled. Claim 5 has been amended to be an independent claim. Claims 10-13 have been amended to be dependent on claim 5. Claims 16 has been canceled. Claim 17 was dependent on claim 14, but has not been amended to be an independent claim. Applicants respectfully submit that claim 24, as amended, is not indefinite. Claims 25-26 depend from claim 24. Applicants therefore respectfully submit that claims 25-26 are not dependent from an indefinite claim. Therefore, Applicants respectfully submit that claims 5, 10-13, 17, and 25-26 are not indefinite. Accordingly Applicants respectfully request that this rejection under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

#### **V. REJECTION UNDER 35 U.S.C. § 101**

The Examiner has rejected claims 1, 3, 5, 10-14, 16-18, 20, and 24-28 under 35 U.S.C. § 101, because the invention allegedly is not supported by either a specific and substantial utility or a well established utility.

Applicants disagree with the Examiner's contentions. As set out in the specification on page 3, lines 29-32:

Voltage-dependent Na<sup>+</sup> channels have long been recognised as targets for anti-arrhythmic and local anaesthetic drugs. Since the mid-1980s, Na<sup>+</sup> channels have become widely accepted as the primary target of anticonvulsants with pharmacological profiles similar to those of phenytoin, carbamazepine, and lamotrigine.

Moreover, the invention also provides for methods of screening for agonist and antagonist molecules or substances of sodium channels (see e.g., page 35, line 30, bridging to page 36, line 5). Thus, the claimed nucleotides can be used to create recombinant cells that can be used to screen for therapeutic pharmaceuticals that can be used as anti-convulsants. Claims 1, 3, 14, and 18 have been canceled. As such, Applicants respectfully submit that claims 5, 10-13, 16-17, 20, and 24-28 are supported by a specific and credible utility. Accordingly Applicants respectfully request that this rejection under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

**IV. REJECTION UNDER FIRST PARAGRAPH OF 35 U.S.C. § 112 -  
ENABLEMENT**

The Examiner has rejected claims 1, 3, 5, 10-14, 16-18, 20, and 24-28 under 35 U.S.C. § 112, first paragraph, for lack of enablement, because the invention allegedly is not supported by either a specific and substantial utility or a well established utility.

Applicants respectfully submit that the claimed invention can be carried out without undue experimentation. First the claimed invention is supported by a specific and credible utility (see section III above). Moreover, one of skill in the art can make and use the claimed nucleotides. That some experimentation and screening of nucleotides may be necessary does not mean that the claims are not enabled, as such screening is routine in the art. In addition, Applicants respectfully submit that new claim 39 which does not contain an identity limitation is enabled. Applicants respectfully maintain that the claims, as amended, are sufficiently enabled under 35 USC § 112, first paragraph. Accordingly Applicants respectfully request that the enablement rejection under 35 U.S.C. § 112 be withdrawn.

**VII. REJECTION UNDER FIRST PARAGRAPH OF 35 U.S.C. §112 –  
WRITTEN DESCRIPTION**

The Examiner has rejected claims 1, 3, 5, 10-14, 16-18, 20, and 24-28 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description of the genus of claimed polynucleotides.

Applicants respectfully maintain that the claims 5, 10-13, 17, 20, and 24-28, as amended, recite sufficient structural limitations to be adequately described under 35 U.S.C. § 112, first paragraph. Claims 1, 3, 14, and 16 have been canceled. Applicants respectfully submit that claims 5, 10-14, 16-18, 20, and 24-28 now recite sufficient structural limitations to comply with the written description requirement. All of the claims contain a chemical structure (e.g., SEQ ID NO: 2 in claim 5). Thus, the claimed genus of nucleotides has been narrowed to the currently amended claims. Applicants maintain that the combination of the structural features of the nucleic acids recited in the claims, provides sufficient detailed, relevant identifying characteristics to adequately

convey to one of skill in the art that the Applicants were in possession of the claimed invention at the time the application was filed. Accordingly, Applicants respectfully request that the written description rejection under 35 U.S.C. § 112 be withdrawn.

**VIII. REJECTION UNDER 35 U.S.C. § 102(a)**

The Examiner has rejected claims 14-16, and 24 under 35 U.S.C. 102(a) as allegedly being anticipated by Agostino et al. (WO 98/45435).

Applicants have canceled claims 14-16. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(a) be withdrawn.

**CONCLUSION**

In view of the foregoing, Applicants believes that 5, 10-13, 17, 20, 24, and 25-28 are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at 734-622-2095.

Respectfully submitted,

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